

Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Special Nutritionals

ARMS#

12722



8 - OTHER

000001

DEC-22-97 11:33 From [REDACTED]

P.01

Job-211

Necropsy Number [REDACTED]

**DEPARTMENT OF PATHOLOGY  
REPORT OF AUTOPSY**

Autopsy Number [REDACTED]

Name of Decedent: [REDACTED]

Registration Number: [REDACTED]

Age: 21 Sex: M Race/Ethnicity: White

Date/Time of Death: 12/09/97, 8:58 p.m.

Pathologists: [REDACTED] M.D. [REDACTED]

Date/Time of Autopsy: 12/11/97, 7:30 a.m.

**FINAL DIAGNOSIS**

Sudden cardiovascular collapse following training for [REDACTED] (by history) with:

1. Rhabdomyolysis with marked elevated serum and urine myoglobin, hyperkalemia, and modest elevation of creatine kinase.
2. Perimortem elevation of hepatic enzymes and bilirubin with marked congestion of the liver.
3. Perimortem elevation of creatinine.
4. Dehydration with increased concentrations of electrolytes in vitreous humor.

**CAUSE OF DEATH:** Exercise induced rhabdomyolysis**MANNER OF DEATH:** Accident

I hereby certify that I, [REDACTED] M.D., have performed an autopsy on the body of [REDACTED] on 12/11/97, at 7:30 a.m. at the [REDACTED] Hospital Morgue. The body is identified by a toe tag and a wrist bracelet bearing his name and hospital identification number.

Signed: [REDACTED]

M.D.

Necropsy protocol released: 12/17/97

OPTIONAL FORM 88 (7-90)

**FAX TRANS**

Dept./Agency

Fax #

NBN 7840-01-817-7368

000002

57  
ISTRATION

202 205 3126

DEC-22-97 11:33

From [REDACTED]

P 02/10 Job [REDACTED]

Necropsy Number: [REDACTED]

**EXTERNAL EXAMINATION**

The body is that of a very well-developed, muscular white male whose appearance is consistent with the stated age of 21 years. The body is clad in a hospital gown at the time of examination.

The body measures 66 inches (168 cm) and weighs 164.5 lbs (74.8 kg, body mass index = 26.5 kg/m<sup>2</sup>). Rigor mortis is present in both the large and small muscle groups. Livor mortis is posterior, and not blanchable. The body is cool following refrigeration. The scalp hair is brown. There is some facial hair on the chin and upper lip. The eyes have previously been harvested. The ears are unremarkable and do not appear to be pierced. The nose is unremarkable. The cheekbones are prominent. The oral mucosa is atraumatic; the mouth unremarkable. Both upper and lower teeth are present and in good repair. The neck is symmetrical. The chest is symmetrical. The axillae are without masses. The breasts are normal adult male and without masses. The abdomen is flat. There is slight marbling over the right lower quadrant. The external genitalia are those of a normal adult male who is circumcised. The anus and perineum are unremarkable. The back is unremarkable. The extremities are symmetrical and the patient is extremely muscular. The thoracic and abdominal panniculus are both less than 0.5 cm. There is a 0.5 cm raised papule over the dorsum of the left hand. While there is some tenting of the skin, this is difficult to assess accurately.

**SCARS AND TATTOOS:**

There is a 2 1/2 inch polychromatic tattoo on the anterior right upper chest of a [REDACTED] which appears to be dressed in a [REDACTED]

**THERAPEUTIC PROCEDURES:**

The following items of therapeutic intervention are present on the body:

There is an endotracheal tube which enters the mouth and terminates above the carina. There is an intravenous catheter in the left antecubital fossa and second intravenous catheter in the left groin. There are needle puncture wounds over the right antecubital fossa.

**INJURIES:**

There are no external injuries visible.

**INTERNAL EXAMINATION****HEAD:**

Scalp:	Intact and without hemorrhages.
Skull:	No fractures of vault or base of skull.
Dura, Falt, and	
Dural Venous Sinuses:	Intact and free of thrombi.
Epidural/Subdural/	
Subarachnoid Spaces:	No hemorrhages or hematomas.

000003

DEC-22-97 11:33 From: [REDACTED]

03/10 Job-211

Necropsy Number [REDACTED]

**Leptomeninges:** Thin, delicate, and without exudate.  
**Cerebral Hemispheres:** Unremarkable. There is a symmetrical external configuration, although there is some slight swelling of the gyri.  
**Cranial Nerves:** Normally distributed.  
**Arteries at Base of Brain:** Free of atherosclerosis and aneurysms.  
**Cingulate Gyri,**  
**Unci, Cerebellar Tonsils:** No herniation.  
**Brain Weight:** 1,560 g. The brain is fixed in formaldehyde and later sectioning reveals:  
**Cut Surfaces of Cerebral Hemispheres:** Normal relationship of gray to white matter without infarcts, masses, hemorrhages, or other focal lesions.  
**Ventricular System:** Free of blood, dilatation, and compression.  
**Brainstem and Cerebellum:** Free of lesions.

### BODY CAVITIES

**Arrangement of Thoracic and Abdominal Organs:** Normally related. The diaphragm is at the level of the 5<sup>th</sup> rib bilaterally. The liver edge is even with the ensiform and the right costal margin.  
**Pleural Cavities:** Free of fluid accumulations and adhesions.  
Right pleural cavity: Contains minimal fluid.  
Left pleural cavity: Contains minimal fluid.  
No pneumothorax.  
**Pericardial Cavity:** Contains minimal fluid.  
**Peritoneal Cavity:** Contains minimal fluid.

### NECK

There is a 1 x 1 cm area of acute hemorrhage at the lower end of the right sternocleidomastoid muscle. Otherwise the paratracheal soft tissues and anterior muscles of the neck, laryngeal and tracheal cartilages, and cervical vertebrae are without significant injury. The upper airway is free of obstructive food boluses and foreign bodies. The tongue was not examined.

### CARDIOVASCULAR SYSTEM

**Heart Weight:** 360 g.  
**Configuration:** Unremarkable. 000004  
**Pericardial and Epicardial Surfaces:** Smooth and glistening.  
**Coronary Arteries:** Arise within the right and left sinuses of Valsalva. All epicardial arteries are widely patent and free of any detectable atherosclerotic plaque or thrombi. There are three ostia for the right coronary artery. There is the main right coronary artery and two smaller ostia. These

DEC-22-97 11:34 From: [REDACTED]

P.04/10 Job-211

Necropsy Number: [REDACTED]

**Ventricular Cavities:****Thickness of Left****Ventricular Wall:****Right Ventricular Wall:****Myocardium:****Endocardial Surfaces:****Cardiac Valves:**

ostia represent branches which are arising closer to the main ostia rather than coming off the main vessel.

Normally related.

12 mm.

3 mm.

Uniform, red/brown, and without foci of discoloration, softening, or fibrosis.

Smooth and glistening and free of fibrosis.

Smooth, pliable and without deformities or vegetations.

Mitral valve circumference: 105 mm. There is no evidence of redundancy of the leaflets or prolapse of the valve.

Tricuspid valve circumference: 110 mm.

Aortic valve circumference: 60 mm.

Pulmonic valve circumference: 70 mm.

**Interatrial/****Interventricular Septa:****Auricular Appendages:****Thoracic and Abdominal Aorta:****Superior/Inferior Vena Cava:****Pulmonary Trunk:**

Intact.

Free of thrombi.

Intimal surfaces smooth and free of atherosclerosis; no aneurysms or dissections.

Free of thrombi.

Free of emboli.

**RESPIRATORY SYSTEM****Larynx:****Trachea:****Major Bronchi:**

Mucosa smooth and without lesions.

Mucosa smooth and glistening and without exudate or lesions.

Widely patent and free of mucus and exudate. Mucosal surfaces smooth and free of lesions.

**Main Pulmonary Arteries  
and Branches:****Lung Weights:****Pleural Surfaces:****Lung Parenchyma:**

Free of emboli and atherosclerotic plaque.

Right lung: 410 g; Left lung: 560 g.

Smooth, glistening, and without adhesions.

Normally crepitant, spongy, pink-gray parenchyma without congestion. Scant amounts of fluid and blood exude from cut surfaces. There are no infarcts, masses, or foci of consolidation.

000005

DEC-22-97 11:35

From

P.05/10 Job

Necropsy Number

**GASTROINTESTINAL TRACT**

**Esophagus:** Mucosa gray-purple and free of lesions.

**Stomach:** Contains about 50 mL of fluid which is greenish brown. No pill, tablet, or capsule fragments recovered. Mucosa free of ulcers, hemorrhages, and masses.

**Small Intestine:** Duodenal mucosa free of ulcers. Remainder of mucosa free of lesions. Serosal surfaces smooth and glistening and without discoloration or exudate. No intraluminal blood.

**Appendix:** Present and free of lesions.

**Colon and Rectum:** Mucosa free of polyps, diverticula, and masses. Serosal surfaces smooth and glistening and free of discoloration and exudate. No intraluminal blood.

**HEPATOBILLIARY SYSTEM AND PANCREAS**

**Liver:** Weight: 1,520 g. Smooth and glistening capsule. Parenchyma is dark brown and there are geographic light areas located predominantly beneath the capsule. These are about 2 to 3 cm in size and probably represent areas of poor perfusion.

**Gallbladder:** Contains about 50 mL of fluid, dark green, viscous bile and is free of stones. Velvety, bile-stained mucosa without lesions.

**Pancreas:** Light brown, lobular, and uniform; no focal lesions.

**HEMATOPOIETIC/LYMPHATIC SYSTEM**

**Spleen:** Weight: 380 g. Smooth, gray capsule. Spleen is very congested and soft.

**Lymph Nodes:** There is no discernible lymphadenopathy.

**Thymus:** Weight: about 50 g. Capsular surfaces free of petechiae. Parenchyma light brown, lobulated, and uniform; no focal lesions.

**Bone Marrow:** Rib bone marrow is spongy, and yellow-red on cut surface without focal lesions.

000006

Necropsy Number: [REDACTED]

**URINARY TRACT****Kidneys:**

Right kidney weight: 100 g; Left kidney weight: 100 g. Cortical surfaces smooth. Cortices of uniform thickness with well-defined corticomedullary junctions. Calyceal and pelvic mucosal surfaces smooth and free of lesions. Renal arteries and veins widely patent and free of atherosclerotic plaque and thrombi.

**Ureters:**

Not dilated.

**Urinary Bladder:**

Contains about 5 mL of cloudy, off-white urine. Mucosa smooth and free of lesions.

**MALE REPRODUCTIVE SYSTEM****Prostate Gland:**

Without enlargement or nodularity.

**Testes:**

Atraumatic, normally descended. There is no evidence of interstitial fibrosis.

**ENDOCRINE SYSTEM****Pituitary Gland:**

Unremarkable in size, shape, color, and consistency.

**Adrenal Glands:**

Symmetrical configuration. Free of hyperplasia, atrophy, nodularity, and hemorrhage.

**MUSCULOSKELETAL SYSTEM**

Clavicles, ribs, sternum, pelvis, and vertebral column free of fractures and deformities. Skeletal muscles very well-developed.

000007

12. 22. 97

12:26 PM

\*FDA ROCKVILLE MD

P07

DEC-22-97 11:37

From

P.07/10 Job

Necropsy Number:

### PROVISIONAL DIAGNOSES

1. Sudden cardiovascular collapse following training for (by history).
2. Perimortem elevation of liver enzymes, bilirubin, and creatinine.
3. No significant anatomic abnormalities or evidence of traumatic injury.

M.D.

000008



DEC-22-97 11:37

Fro

08/10 Jo

Necropsy Number:

**MICROSCOPIC DESCRIPTION**

- Skeletal muscle:** Sections of biceps (#1), diaphragm (#2), pectoralis (#3), psoas (#4), and quadriceps (#5) were examined microscopically. The biceps show hypertrophy of the skeletal muscle bundles. There are also smaller, angulated fibers between the hypertrophied fibers. Also present are occasional regenerating muscle fibers characterized by smaller fibers with basophilic cytoplasm. There is no acute inflammation or vasculitis. The other muscles are unremarkable.
- Heart:** Unremarkable. There is no evidence of myocarditis.
- Liver:** There is tremendous congestion with expansion of the space of Disse by erythrocytes, some of which are partially lysed. These changes are most prominent in the region of the central vein and resolve as one moves closer to the portal triad. In some areas the central veins are markedly congested. Between the cords of hepatocytes are several blue, spherical shapes which may represent apoptotic hepatocytes.
- Lungs:** Several alveolar spaces are filled with edema fluid but there are no neutrophils. A hilar lymph node has normal architecture.
- Spleen:** Acute congestion with marked expansion of the red pulp by erythrocytes.
- Adrenal:** Unremarkable.
- Pancreas:** Marked autolysis.
- Kidney:** Several of the proximal tubules contain degenerating epithelial cells, however extensive autolysis precludes definitive statements regarding the presence of acute tubular necrosis. No cellular or pigmented casts are present.
- Brain:** Sections of basal ganglia, frontal cortex, pons and cerebellum are unremarkable.
- Bone marrow:** Normocellular with normal, trilinear maturation.
- Testes:** Unremarkable, no evidence of fibrosis. Normal sperm maturation.

000009

DEC-22-97 11:37 From: [REDACTED]

08/10 [REDACTED]

Necropsy Number: [REDACTED]

**TOXICOLOGY / SUBREGIONAL STUDIES**

Blood, bile, urine, gastric contents, liver, and brain are collected and saved.

Blood was obtained within 2 hours of death and the following values obtained:

Test	Normal values	Result	Comment
Total bilirubin	0.1 - 1.1 MG/DL	1.3	High
Aspartate aminotransferase (AST)	2 - 35 IU/L	7473	High
Alanine amino transferase (ALT)	0 - 45 IU/L	9586	High
Lactate dehydrogenase (LDH)	60 - 200 IU/L	10037	High
Alkaline phosphatase (ALK)	30 - 130 IU/L	34	Normal
Urea nitrogen (UN)	8 - 20 MG/DL	33	High
Creatinine	0.9 - 1.3 MG/DL	3.3	High
Sodium	136 - 146 MEQ/DL	147	High
Potassium	3.5 - 5.0 MEQ/DL	12.1	Critical
Creatine kinase (CK)	30 - 240 IU/L	366	High
Aldolase	1 - 7 IU/L	352	High
Troponin I	0.0 - 1.5 NG/ML	1.8	High
Myoglobin	0 - 110 NG/ML	>5000	High

The following values were obtained from the vitreous humor, approximately 4 hours after death

Test	Normal values, <i>plasma</i>	Result	Comment
Creatinine	0.9 - 1.3 MG/DL	0.7	Low
Sodium	136 - 146 MEQ/DL	159	High
Potassium	3.5 - 5.0 MEQ/DL	6.9	High
Urea nitrogen (UN)	8 - 20 MG/DL	31	High
Chloride	99 - 111 MEQ/L	143	High

The following results were obtained from urine at autopsy, approximately 36 hours after death.

Test	Normal values	Result	Comment
Myoglobin	0 - 45 NG/ML	4280	High
Drug screen for: Amphetamines; Barbiturates; Benzodiazepines; Cannabinoids; Cocaine; Opiates	Negative	Negative for all drugs	

000010

DEC-22-97 11:37

From [REDACTED]

P.10/10 Job [REDACTED]

Necropsy Number: [REDACTED]

Blood obtained 36 hours after death was submitted for anabolic-androgenic steroids  
Specimen submitted was analyzed by Gas Chromatography-Mass Spectrometry techniques for the  
following steroids and metabolites:

Bolasterone, Methyltestosterone, Boldenone, Norethandrolone, 4-Chlorotestosterone, Norethindrone,  
Fluoxymesterone (Halotestin), Nandrolone (19-Nortestosterone), Furazabol, Oxandrolone (Anavar),  
Mesterolone, Oxymesterone (Theranabol), Methandienone (Dianabol), Oxymetholone (Androl),  
Methandriol, Stanozolol, Methenolone (Primonabol)

Specimen was analyzed by Gas Chromatography-Mass Spectrometry techniques  
for the following additional agents:  
Probenecid (Benemid)...Blocking/Masking Agent  
Clenbuterol...Anti-Catabolic Agent

**Profile Results****Test Results: No Drugs Detected**

Results from [REDACTED]

**BRIEF SUMMARY OF CIRCUMSTANCES OF DEATH**

Please refer to [REDACTED]

000011

JAN-27-98 14:44 From [REDACTED]

P.01/07 Job [REDACTED]

January 23, 1998

OPTIONAL FORM 88 (7-80)

**FAX TRANSMITTAL**

# of pages →

To <b>BETH YEATLEY</b>	From
Dept./Agency	Phone #
Fax # <b>202-205-5295</b>	Fax #

By FAX: [REDACTED]

**POSTMORTEM FORENSIC TOXICOLOGY REPORT IN THE CASE OF:**

[REDACTED] 21/M/W, 66", 164.5 lbs.

[REDACTED] Registry # [REDACTED]

[REDACTED] Control No [REDACTED]

[REDACTED] Accession No [REDACTED]

A. Specimens received a [REDACTED] on 01/13/98 in sealed and labeled containers: ~5 mL Bile, ~1.5 mL "PM Blood", ~5 mL Heart Blood, ~5 g Liver, ~3 g Brain and ~2 mL Urine.

B. History: Collapse, associated with strenuous, prolonged [REDACTED] training pre-weight-in exercise.

C. Stated (available) Substances (prescribed and over the counter):

Thermogenics-Plus™ ("nutritional supplement): Ma huang (Ephedrine), Caffeine, other minerals & herbs

Aspirin

Aleve™ (naproxen sodium)

Vicodin™ (Hydrocodone & Acetaminophen)

Flexeril™ (Cyclobenzaprine)

ProChrome II Gel Tabs (Chromium, 0.5 mg)

Ibuprofen (Remote)

D. Forensic Toxicologic Examination

I. Verification/Negation of stated potentially causally involved substances and Vehicles

II. Surveys for related, potentially causally involved substances

III. Exclusion of common "sudden death" poisons and common "abuse" substances

000012

Page TwoE. Analyses on Bile and Blood (& fees)

8292L Ephedrine & Pseudoephedrine by GC/NPD & GC/MS in Bile:	\$ 97.00
in Blood:	\$ 70.00
7004L Caffeine by GC/NPD in Bile:	\$ 57.00
in Blood:	\$ 28.00
7005L Methylxanthines, Acetaminophen, Acetazolamide & Methazalone Survey by HPLC in Bile:	\$ 87.00
8663 Hydrocodone by GC/MS in Bile (includes also: Codeine, Dihydrocodeine, Hydromorphone, Morphine, 6-MAM, Oxycodone & Oxymorphone):	\$131.00
9260 Salicylates in Bile:	\$ 52.00
1405L Cyclobenzaprine by GC/NPD in Bile:	\$ 63.00
3223L NSAIDS Survey by HPLC for: Diclofenac, Etodolac, Fenoprofen, Flubiprofen, Ibuprofen, Indomethacin, Ketoprofen, Ketorolac, Meclofenamate, Mefenamate, Naproxen, Oxyphenbutazone, Phenylbutazone, Piroxicam & Tolmetin in Bile:	\$ 191.00
1893L Extractable organics survey for CPR adjunct drugs, and potentially acutely toxic levels of relatively common extractable organic medicinals and environmental toxicants by GC/NPD in Bile:	\$ 88.00
2321L Organovolatile inhalants & intoxicants with boiling points up to approximately 180°C by Headspace Gas Chromatography in Bile:	\$ 67.00

F. Extractable Organics Survey on Urine by GC/NPD with GC/MS delineation of (presumptive) positive test results (Microanalyses): \$ 88.00

G. Results:I. Positive Test Resultsa. Bile

1. Ephedrine: 40 nanog/mL (0.04 mg/L)
2. Pseudoephedrine: 20 nanog/mL (0.02 mg/L)

Both drugs are constituents of ma huang.

Their usual (individual) doses are approximately 10-50 mg.

Half-lives are 5-7 ¼ hours for ephedrine and 3-16 hours (pH dependent) for pseudoephedrine

3. Lidocaine: 70 nanog/mL (0.07 mg/L)

Lidocaine is commonly used by injection as a cardioregulatory drug to assist in CPR. Its elimination half-life is 1½-2 hours.

000013

Page Three

4. Dihydrocodeine: ~ 0.7 mg/L Bile  
Hydrocodone: ~ 0.6 mg/L Bile
5. Salicylate: Not more than 5 mg/L Bile
6. Naproxen: ~ 0.9 mg/L Bile

This is a non-steroidal anti-inflammatory with a half-life of 10-20 hours.

7. Cyclobenzaprine: More than 1 mg/L Bile

This is used as a centrally acting skeletal muscle relaxant at daily 30-60 mg doses. Its half-life is 24-72 hours. In fatal poisonings, 5-12 mg/L Bile have been reported. Overdoses can cause (i.e.) arrhythmias.

b. Blood

1. Possible traces of Lidocaine (less than 10 mcg/L, if any) and of Caffeine (less than 100 mcg/L) by GC/NPD. These presumptive trace concentrations are too low to be confirmable by GC/MS. In fact, GC/MS did not give confirming results.

c. Urine

6 mg Caffeine/L

1 mg Lidocaine/L

H. Comment

- 1) None of the levels of the substances found are in the strictly dose dependent, potentially acutely toxic range.
- 2) The demonstrated residual presence of ephedrine, pseudoephedrine and caffeine is congruent with "nutritional supplements" of the excitant stimulant types stated as having been used regularly by the deceased.
- 3) In the light of this and the extreme sweating activities described, effects of the ephedrine, pseudoephedrine and caffeine may have contributed to cardiac events of this death.

Sincerely yours,

[REDACTED]  
Ph.D., [REDACTED]

000014

5-Jun-98

POSTMORTEM FORENSIC TOXICOLOGICAL ANALYSES FOR EPHEDRINE,  
PSEUDOEPHEDRINE, METHYLEPHEDRINE AND PHENYLPROPANOLAMINE

[REDACTED]  
[REDACTED]

SPECIMEN	EPHEDRINE	PSEUDO-EPHEDRINE	METHYL-EPHEDRINE	PHENYL-PROPANOLAMINE	GC/MS REPORTING LIMIT (nanog/mL)*	LC/MS REPORTING LIMIT (nanog/mL)
BILE	13 nanog/mL	9.7 nanog/mL	none detected	none detected	20	5

000015

\*Reporting Limits for all analytes except methylephedrine